CLAIM AMENDMENTS

1. (original) A solid dispersion comprising an active ingredient selected among tacrolimus and analogues thereof dispersed or dissolved in a hydrophilic or water-miscible vehicle, wherein the melting point of the vehicle is at least 20°C and the active ingredient is present therein in a concentration of between about 0.01 w/w% and about 15 w/w% to form a solid dispersion or solid solution at ambient temperature.

2. (original)The solid dispersion according to claim 1, wherein the analogue exhibits pharmacological and/or therapeutical activity at least equivalent to that of tacrolimus.

3. (original) The solid dispersion according to claim 1, wherein the active ingredient is partly dissolved in the vehicle to form a mixture of solid dispersion and solid solution at ambient temperature.

4. (original) The solid dispersion according to claim 1, wherein the active ingredient is fully dissolved in the vehicle to form a solid solution at ambient temperature.

5. (original) The solid dispersion according to claim 1, wherein the hydrophilic or water-miscible vehicle has a melting point of at least 30°C.

6. (original) The solid dispersion according to claim 1, wherein the concentration of the active ingredient in the hydrophilic or water-miscible vehicle is at the most 10w/w%.

7. (original) The solid dispersion according to claim 1, wherein the concentration of the active ingredient in the hydrophilic or water-miscible vehicle is at least about 0.05w/w%.

8. (original) The solid dispersion according to claim 1, wherein at least 50 w/w% of the active pharmaceutical ingredient is released within about 30 minutes, when tested in any dissolution test according to USP using an aqueous dissolution medium.

9. (original) The solid dispersion according to claim 1, wherein at least 75 w/w% of the active pharmaceutical ingredient is released within about 40 minutes, when tested in any dissolution test according to USP using an aqueous dissolution medium.

10. (original) The solid dispersion according to claim 1, wherein at least 90 w/w% of the active pharmaceutical ingredient is released within about 60 minutes, when tested in any dissolution test according to USP using an aqueous dissolution medium.

11. (original) The solid dispersion according to claim 1, wherein the hydrophilic or water-miscible vehicle is selected from the group consisting of polyethylene glycols, polyoxyethylene oxides, poloxamers, polyoxyethylene stearates, poly-epsilon caprolactone, polyglycolized glycerides such as Gelucire®, and mixtures thereof.

12. (original) The solid dispersion according to claim 1, wherein the hydrophilic or water-miscible vehicle is selected from the group consisting of polyvinylpyrrolidones, polyvinyl- polyvinylacetate copolymers (PVP-PVA), polyvinyl alcohol (PVA), polymethacrylic polymers (Eudragit RS; Eudragit RL, Eudragit NE, Eudragit E), cellulose derivatives including hydroxypropyl methylcellulose (HPMC), hydroxypropyl

cellulose (HPC), methylcellulose, sodium carboxymethylcellulose, hydroxyethyl cellulose, pectins, cyclodextrins, galactomannans, alginates, carragenates, xanthan gums and mixtures thereof.

13. (original) The solid dispersion according to claim 1, wherein the vehicle is a polyethylene glycol (PEG).

14. (original) The solid dispersion according to claim 13, wherein the polyethylene glycol has an average molecular weight of at least 1500.

15. (original) The solid dispersion according to claim 1 comprising a mixture of two or more hydrophilic or water-miscible vehicles.

16. (original) The solid dispersion according to claim 15, wherein the mixture comprises a polyethylene glycol and a poloxamer in a proportion of between 1: 3 and 10: 1, preferably between 1: 1 and 5: 1, more preferably between and 3: 2 4: 1, especially between 2: 1 and 3: 1, in particular about 7: 3.

17. (original) The solid dispersion according to claim 16, wherein the poloxamer is poloxamer 188.

18. (original) The solid dispersion according to claim 16, wherein the polyethylene glycol has an average molecular weight of about 6000 (PEG6000).

19. (currently amended) A ~~pharmaceutical~~ composition comprising the solid dispersion according to claim 1 and one or more pharmaceutically acceptable excipients.

20. (currently amended) The ~~pharmaceutical~~ composition according to claim 19, wherein the pharmaceutically acceptable excipients are selected from the group consisting of fillers, disintegrants, binders and lubricants.

21. (currently amended) The ~~pharmaceutical~~ composition according to claim 19 in particulate form, for example in powder form.

22. (currently amended) The ~~pharmaceutical~~ composition according to claim 21, wherein the particles have a geometric weight mean diameter d_{gw} from about 10 um to about 2000 um, preferably from about 20 um to about 2000 um, especially from about 50 um to about 300 um.

23. (currently amended) The ~~pharmaceutical~~ composition according to claim 21, wherein the particles have a geometric weight mean diameter d_{gw} from about 50 um to about 300 um.

24. (currently amended) A dosage form comprising the ~~pharmaceutical~~ composition according to claim 19, which is a solid oral dosage form.

25. (original) The dosage form according to claim 24, which is a unit dosage form.

26. (original) The dosage form according to claim 24, which further comprises a pharmaceutically acceptable additive selected from the group consisting of flavoring agents, coloring agents, taste-masking agents, pH-adjusting agents, buffering agents, preservatives, stabilizing agents, anti-oxidants, wetting agents, humidity-adjusting agents, surface-active agents, suspending agents, absorption enhancing agents and release modifying agents.

27. (original) The dosage form according to claim 24, wherein at least one pharmaceutical acceptable excipient is selected from the group consisting of silica acid or a derivative or salt thereof including silicates, silicon dioxide and polymers thereof; magnesium aluminosilicate and/or magnesium aluminometasilicate, bentonite, kaolin, magnesium trisilicate, montmorillonite and/or saponite.

28. (original) The dosage form according to claim 24, wherein at least one pharmaceutically acceptable excipient is a silica acid or a derivative or salt thereof.

29. (original) The dosage form according to claim 24, wherein at least one pharmaceutical acceptable excipient is silicon dioxide or a polymer thereof.

30. (original) The dosage form according to claim 29, wherein the silicon dioxide product has properties corresponding to Aeroperl® 300, (available from Degussa, Frankfurt, Germany).

31. (original) The dosage form according to claim 26 comprising one or more release modifying agents selected from the group consisting of water-miscible polymers, water-insoluble polymers, oils and oily materials.

32. (original) The dosage form according to claim 31, wherein the water-insoluble polymer is selected from the group consisting of ethyl cellulose, cellulose acetate, cellulose nitrate, and mixtures thereof.

33. (original) The dosage form according to claim 31, wherein the oil or oily material is selected from the group consisting of hydrophilic and hydrophobic oils or oily materials.

34. (original) The dosage form according to claim 31, wherein the oil or oily material is hydrophilic and selected from the group consisting of polyether glycols such as polypropylene glycols ; polyoxyethylenes; polyoxypropylenes ; poloxamers ; polyglycolized glycerides such as Gelucire® and mixtures thereof.

35. (original) The dosage form according to claim 34, wherein Geluciree is selected among Gelucire®; 50/13, Gelucire® 44/14 etc., Gelucire® 50/10, Gelucire® 62/05 and mixtures thereof.

36. (original) The dosage form according to claim 31, wherein the oil or oily material is hydrophobic and selected from the group consisting of straight chain saturated hydrocarbons, sorbitan esters, paraffins; fats and oils such as cacao butter, beef tallow, lard, polyether glycol esters; higher fatty acid such as stearic acid, myristic acid, palmitic acid, higher alcohols such as cetanol, stearyl alcohol, low melting point waxes such as

glyceryl monostearate, glyceryl monooleate, hydrogenated tallow, myristyl alcohol, stearyl alcohol, substituted and/or unsubstituted monoglycerides, substituted and/or unsubstituted diglycerides, substituted and/or unsubstituted triglycerides, yellow beeswax, white beeswax, carnauba wax, castor wax, japan wax, acetate monoglycerides ; NVP polymers, PVP polymers, acrylic polymers, and mixtures thereof.

37. The dosage form according to claim 36, wherein the oil or oily hydrophobic material has a melting point of at least about 20°C.

38. (original) The dosage form according to claim 31, wherein the water-miscible polymer is a cellulose derivative selected from the group consisting of hydroxypropyl methylcellulose (HPMC), hydroxypropyl cellulose (HPC), methylcellulose, sodium carboxymethylcellulose, hydroxyethyl cellulose, poloxamers, polyoxyethylene stearates, poly-s-caprolactone, polyvinylpyrrolidone (PVP), polyvinylpyrrolidone-polyvinylacetate copolymer PVP-PVA, polymethacrylic polymers and polyvinyl alcohol (PVA), poly (ethylene oxide) (PEO) and mixtures thereof.

39. (original) The dosage form according to claim 38, wherein the polymethacrylic polymers are selected among Eudragit® RS, Eudragit® RL, Eudragit® NE and Eudragit E.

40. (original) The dosage form according to claim 31, which is entero-coated using a water-miscible polymer having a pH-dependant solubility in water.

41. (original) The dosage form according to claim 40, wherein the water-miscible polymer is selected from the group consisting of polyacrylamides; phthalate derivatives such as acid phthalate of carbohydrates including amylose acetate phthalate, cellulose acetate phthalate, cellulose acetate terephtahalate, cellulose acetate isophthalate, other cellulose ester phthalates, cellulose ether phthalates, hydroxypropyl cellulose phthalate, hydroxypropylcellulose acetate phthalate, hydroxypropyl ethylcellulose phthalate, hydroxypropyl methylcellulose phthalate (HMPCP), methylcellulose phthalate, methyl cellulose acetate phthalate, polyvinyl acetate phthalate, polyvinyl acetate hydrogen phthalate, sodium cellulose acetate phthalate, starch acid phthalate ; phthalate of other compounds including polyvinyl acetate phthalate (PVAP); other cellulose derivatives including hydroxypropyl methylcellulose acetate succinate (HPMCAS), carboxymethylcellulose, cellulose acetate trimellitate ; alginates ; carbomers; polyacrylic acid derivatives such as acrylic acid and acrylic ester copolymers, polymethacrylic acid and esters thereof, poly acrylic methacrylic acid copolymers, methacrylic acid copolymers (for example Eudragit L and Eudragite S); styrene-maleic acid dibutyl phthalate copolymer, styrene-maleic acid polyvinylacetate phthalate copolymer, styrene and maleic acid copolymers ; shellac, starch glycolat ; polacrylin ; vinyl acetate and crotonic acid copolymers and mixtures thereof.

42. (original) The dosage form according to claim 40, which upon oral administration to a mammal in need thereof releases at the most about 10 w/w%, preferably at the most about 7.5 w/w%, more preferably at the most about 5 w/w%, especially at the most about 2 w/w% of the total amount of active ingredient within the first 3 hours, preferably within 2 hours, more preferably within 1 hours, in particular within about 30 minutes after administration.

43. (original) The solid dosage form according to claim 24, wherein the solid dosage form upon oral administration to a mammal in need thereof is essentially bioequivalent with Prografs or a similar commercially available tacrolimus-containing product when

administered in a dose that is at the most about 85% w/w of the dose of tacrolimus administered in the form of Prograf® or a similar commercially available tacrolimus-containing product.

44. (original) The solid dosage form according to claim 24, wherein the solid dosage form upon oral administration to a mammal in need thereof releases at least about 50% w/w of the active ingredient within 24 hours, preferably within about 20 hours, more preferably within about 18 hours, especially within about 15 hours, in particular within about 12 hours.

Claims 45-50 (canceled)

51. (original) A method for the preparation of the solid dispersion according to claim 1, the method comprising the step of dispersing and/or dissolving tacrolimus or an analogue thereof in a hydrophilic or water-miscible vehicle to obtain a solid dispersion and/or solid solution at ambient temperature.